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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,693	02/02/2001	Mike A. Clark	PHOE-0060	9010

23377 7590 12/22/2003  
WOODCOCK WASHBURN LLP  
ONE LIBERTY PLACE, 46TH FLOOR  
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PHILADELPHIA, PA 19103

EXAMINER
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DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/775,693	Applicant(s) KUMAR, BINOD	
	Examiner MINH-TAM DAVIS	Art Unit 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/02/03.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6,7,27 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,27 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
        1. ☐ Certified copies of the priority documents have been received.  
        2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
    \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
    a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1-2, 6-7, 27, 31-36 are being examined.

The following are the remaining rejections.

### **REJECTION UNDER 35 USC 103**

Rejection under 35 USC 103 of claims 1-2, 6-7, 27, 31-36 pertaining to being obvious over US 5,804,183 in view of Takaku, H et al, 1995, Jpn. J Cancer Res, 86: 840-846, IDS# AM, in paper No:6, on 06/19/01, Sugimura, K, et al, 1992, Melanoma Res, 2: 191-196, IDS# AK, in paper No:6, on 06/19/01 , and Oyanagi, K et al, 1986, Tohoku J Exp Med (Japan), 148 (4): 385-91, remains for reasons already of record in paper No.18.

Applicant argues that the combination of the cited references fails to teach or suggest every limitation of the claims. Applicant argues that the claims are drawn to methods for identifying cancer patients susceptible to arginine deprivation therapy, comprising detecting the presence or absence of arginosuccinate synthetase protein in a cancerous tumor sample, and that the combined references do not disclose, teach or suggest the claimed method. Applicant asserts that the Office must provide objective evidence of a suggestion or incentive that would have motivated those of ordinary skill in the art to combine the cited references. Applicant asserts that the Office must

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demonstrate that the proposed combination would have had a reasonable expectation of success.

Applicant's arguments set forth in paper No. have been considered but are not deemed to be persuasive for the following reasons:

Contrary to Applicant's arguments, the combination of the cited references suggests every limitation of the claims.

Although the references do not directly teach methods for identifying cancer patients susceptible to arginine deprivation (AD) therapy, however, it would have been obvious to identifying cancer patients susceptible to arginine deprivation therapy, comprising detecting the presence or absence of arginosuccinate synthetase protein in a cancerous tumor sample for the following reasons:

**1) Not all tumor cells are susceptible to arginine deprivation (AD) therapy,** because the AD sensitivity of various tumor cells is attributed to the reduced level of argininosuccinate synthetase expression, as taught by Sugimura et al, and

**2) Cancers such as carcinoma, melanoma or hepatoma that have been** successfully treated by arginine deprivation (AD) therapy, all are deficient in or have reduced level of arginosuccinate synthetase, as taught by US 5,804,183, Takaku et al, and Oyanagi et al.

In other words, one would have been motivated to identify cancer patients that could be treated by arginine deprivation (AD) therapy, because not all tumor cells could be treated with arginosuccinate synthetase, as taught by Sugimura et al. Further, one would have been motivated to identify cancer patients that could be treated by arginine

deprivation (AD) therapy, by detecting the level of arginosuccinate synthetase, because the reduced level of arginosuccinate synthetase is correlated with susceptibility to arginine deprivation (AD) therapy, as taught by US 5,804,183, Takaku et al, and Oyanagi et al.

The motivation is to identify cancer patients that could be treated by arginine deprivation (AD) therapy for commercial benefit.

The idea of combining the above cited references clearly flows logically from their having been individually taught in the art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

December 09, 2003

